

REMARKS

The present response is intended to be fully responsive to all points of objections and rejections raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested. Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 66-100, 102-104 and 110-122 have been rejected. Claims 66 and 95 have been amended.

Claims 75-77, 97-100, and 122 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicant reserves all rights in these claims to file divisional and/or continuation patent applications.

Claim rejections - 35 USC § 112

Claim 122 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. The Examiner's rejection is now moot due to the cancellation of claim 122.

Claim rejections - 35 USC § 103(a)

Claims 66-74, 76-89, 91, 95, 96, 98-100, 102, 104 and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) in view of Baghdassarian (USP #2003/0050567).

Amended claim 66 is directed to a system for collecting a plurality of samples of breath of a subject the system comprising an oral/nasal cannula adapted to convey exhaled breath from the subject, a pump for collecting said exhaled breath from the subject by means of its suction effect, a carbon dioxide sensor for determining carbon dioxide level in said exhaled breath, wherein said sensor is adapted to provide a signal indicative of said carbon dioxide level in said exhaled breath, wherein said signal triggers the commencement of collection of samples of at least part of said exhaled breath, a plurality of sample containers for collection of said plurality of samples, and a sample distributor adapted to receive said breath motioned by

said pump and to direct different collected samples of said exhaled breath to different ones of said plurality of sample containers.

Amended claim 95 is directed to a system for collecting a plurality of samples of breath of a subject comprising an oral/nasal cannula adapted to convey exhaled breaths from the subject to said system, a pump for collecting said breath from the subject by means of its suction effect, a plurality of sample containers for collection of said plurality of samples, a capnographic analyzer for determining carbon dioxide concentration in said exhaled breaths of the subject, a controller adapted to receive input at least from said capnographic analyzer, a sample distributor which is adapted to receive said breath motioned by said pump and to direct different predetermined samples of said exhaled breaths to different ones of said plurality of sample containers, according to said controller, and a valving system adapted to select at least part of one of said exhaled breaths to said sample distributor according to said capnographic analyzer.

The use of a pump, as disclosed in amended claims 66 and 95, allows the collection of exhaled breath from the subject (for example, continuous collection) without the need of the subject's cooperation, for example, without the need to request the subject to blow. In this way, not just exhaled breaths are collected and introduced into the system but a constant flow of air from the subject. The pump is adapted to allow sucking breath from the subject using an oral/nasal cannula and without the need of the subject blowing, for example to a tube or a mouthpiece.

Applicant asserts that Lemelson does not teach or suggest a system for collecting a plurality of samples of breath of a subject wherein the system includes a pump for collecting the exhaled breath from the subject by means of its suction effect, as recited in amended claims 66 and 95. In contrast, Lemelson discloses that the "breath samples are collected by breathing into the mouthpiece" [Column 3 lines 28-29]. Lemelson device's lack of a pump requires a mouthpiece for collecting the exhaled breath in order to operate. Furthermore, Lemelson's device, lacking a pump, requires the active breathing of a subject for its operation "the inlet valve is opened by the pressure of the breath" [Column 2 lines 36-37].

Applicant further asserts that Baghdassarian does not teach or suggest a system for collecting a plurality of samples of breath of a subject wherein the system includes a pump for collecting the exhaled breath from the subject by means of its suction effect, as recited in amended claims 66 and 95. In contrast, Baghdassarian discloses "A mouthpiece ... large

enough to cover an individual's mouth ..." for collecting the breathing of the individual, whether the breathing is artificial or non-artificial [paragraph 35], meaning that a lack of a pump for sucking air from the subject requires a mouthpiece for covering the mouth for collecting the breathing. Although Baghdassarian does disclose the use of a pump as the Examiner indicated, the pump is connected to the reservoir and is adapted to draw the alveolar breath from the sampling chamber to the reservoir [paragraphs 38-39] and not for sucking breath from the subject.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since Lemelson or Baghdassarian, alone or in combination, do not teach or suggest all the elements of any of amended independent claims 66 and 95 and dependent claims 67-74, 78-94, 96, 103-104 and 120-121, the Examiner fails to establish a *prima facie* showing that Lemelson or Baghdassarian, alone or in combination, teach or suggest every feature of amended independent claims 66 and 95 and dependent claims 67-74, 78-94, 96, 103-104 and 120-121.

Claims 75 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) and Baghdassarian (USP #2003/0050567) in view of Dietz (USP #5,005,571).

Claims 75 and 97 have been canceled. The Examiner's rejection is now moot due to the cancellation of claims 75 and 97.

Claims 90 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) and Baghdassarian (USP #2003/0050567) in view of Opekun (USP #5,140,993).

Applicant asserts that Opekun does not teach or suggest a system for collecting a plurality of samples of breath of a subject wherein the system includes a pump for collecting the exhaled breath from the subject by means of its suction effect, as recited in amended claims 66 and 95. In contrast, Opekun discloses "The inlet mechanism through which a patient exhales..." for collecting the breath [column lines 36-38], which in effect requires the exhaling of the subject.

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since Lemelson, Baghdassarian, and Opekun, alone or in combination, do not teach or all the elements of any of amended independent claims 66 and 95 and dependent claims 90 and 103, the Examiner fails to

establish a *prima facie* showing that Lemelson, Baghdassarian, or Opekun, alone or in combination, teach or suggest every feature of amended independent claims 66 and 95 and dependent claims 90 and 103.

Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) and Baghdassarian (USP #2003/0050567) in view of Daniels (USP #6,099,481).

Applicant asserts that Daniels does not teach or suggest a system for collecting a plurality of samples of breath of a subject wherein the system includes a pump for collecting the exhaled breath from the subject by means of its suction effect, as recited in amended claims 66 and 95. In contrast, Daniels discloses a system for detecting and processing data of various respiratory flow and blood gas parameters. The disclosed apparatus monitors respiratory flow and blood gas data to detect air flow pressures, air flow volumes, partial carbon dioxide pressure, and other breath characteristics [column 2 line 64 – column 3 line 2]. The disclosed method is then employed to analyze the collected data, process the data to derive values for other respiratory characteristics, and display the collected and derived data [column 3 lines 3-5].

An obviousness rejection requires a teaching or a suggestion by the relied upon prior art of all the elements of a claim (M.P.E.P. §2142). Since Lemelson, Baghdassarian, or Daniels alone or in combination, do not teach or all the elements of any of amended independent claims 66 and 95 and dependent claims 92-94, the Examiner fails to establish a *prima facie* showing that Lemelson, Baghdassarian, or Opekun, alone or in combination, teach or suggest every feature of amended independent claims 66 and 95 and dependent claims 92-94.

Accordingly, Applicant respectfully requests that the rejection of claims 66-74, 76-89, 91, 95, 96, 98-100, 102, 104 and 120-122 under 35 USC 103(a) be withdrawn.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Respectfully submitted,

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Date

/Rodney J. Fuller/
Rodney J. Fuller (Reg. No. 46,714)

FENNEMORE CRAIG
Customer No. 27,887

602-916-5404